K103247

DEC 10 2010

Section 5. 510(k) Summary

APPLICANT
[As Required by 21 CFR 807.92 a(1)]

Applicant:	ThermoTek, Inc.
Address:	1200 Lakeside Parkway, #200 Flower Mound, Texas 75028
Telephone Number:	972-874-4949 972-874-4945 (fax)
Company Contact:	Niran Balachandran Director of Engineering
Date:	April 28, 2010

DEVICE NAME
[As Required by 21 CFR 807.92 a(2)]

Proprietary Name:	VascuComp™
Common Name:	Intermittent, External Pneumatic Compression Device
Device Classification:	Class II
Regulation Number:	870.5800
Product Code:	JOW
Device Panel:	Cardiovascular

IDENTIFICATION OF PREDICATE DEVICES
[As Required by 21 CFR 807.92 a(3)]

BioCompression Systems, Inc., BioArterial Plus	K072666
ThermoTek Inc., VascuTherm	K061866
PBS (Petit Basci System) Model 701A	K060220

DEVICE DESCRIPTION
[As Required by 21 CFR 807.92 a(4)]

Intended Use

The VascuComp™-01 and VascuComp™-02 is a new device that is intended to function as an intermittent, sequential pneumatic compression device. It is intended to provide the following therapeutic functions:

1. **VascuComp™ AI Mode:** Increase arterial inflow to lower limbs of those with ischemic disease of the lower extremities.
2. **VascuComp™ DVT Mode:** Decrease the risk of deep venous thrombosis (DVT) by aiding blood flow back to the heart via lower extremity limb compression.
3. **VascuComp™ L Mode:** Intended to aid in the treatment of Venous disorders and dysfunction of the "muscle pump".

Physical Description

The VascuComp™ device is comprised of a reusable air-pump with user adjustable pressures, and various single-patient sleeves or garments containing discrete, segmental inflatable chambers to be externally applied over the affected extremity of the patient.

Therapy Modality Used

The Vascu Comp™ provides calibrated, intermittent, sequential compression to the treatment site for optimum therapy for patients with ischemic disease of the lower extremities, by increasing arterial circulation, and to reduce the risk of the formation of DVT and to reduce or control peripheral edema.

Safety Features

The Vascu Comp™ systems utilize microprocessor control with multiple sensors to ensure patient safety and system functionality, and to provide consistent and repeatable therapy modalities. Alarms are both visual on the unit display and audible. Alarms are in place to detect a potentially unsafe situation and to terminate therapy to protect the patient and the system.

STATEMENT OF INTENDED USE
[As Required by 21 CFR 807.92 a(5)]

Vascu Comp™ Indications for Use:

VascuComp™ AI Mode:

The VascuComp™ compression system in AI Mode is used as an adjunct therapy for patients with ischemic disease of the lower extremities, due to one or more of the following causes:

- Minor Amputations
- Angioplasty / Stent Failure
- Arteriopathic Wounds
- Graft Failure
- Intermittent Claudication
- Ischemia
- Night Pain
- Rest Pain
- Small Vessel Disease
- Ulcers

VascuComp™ DVT Mode:

- Decrease the risk of deep venous thrombosis (DVT).
- Aids the blood flow back to the heart.
- Treat and assist healing of cutaneous ulceration (wounds), reduce wound healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.

VascuComp™ L Mode:

- Treatment of Venous disorders and dysfunction of the "muscle pump".

TECHNOLOGICAL CHARACTERISTICS
[As Required by 21 CFR 807.92 a(6)]

The Vascu Comp™ compression device has the same technical and performance characteristics as the predicate devices.

The pneumatic control circuitry is a microprocessor-controlled system. Multiple safety redundancies are built into the system including: alarms for open and blocked airflow detection and for unit malfunction situations.

The Vascu Comp™ compression device is powered from a 110 or a 220 ± 10% VAC source. It also incorporates an ergonomic, intuitive user interface for ease of use and to customize treatment parameters.

Comparison of features and principles of operation between Vascu Comp™ and predicate devices per Section 510(k) of the Act.

VascuComp™ AI Mode:

Parameter	VascuComp™ Compression Device	Bio Compression Systems, Inc., BioArterial Plus (K072666)
Intended use	Intermittent Sequential Pneumatic Compression	Intermittent Sequential Pneumatic Compression
Indications for Use	The VascuComp™ compression system in AI Mode is used as an therapy device for patients with ischemic disease of the lower extremities, due to one or more of the following causes: Minor Amputations Angioplasty / Stent Failure Arteriopathic Wounds Graft Failure Intermittent Claudication Ischemia Night Pain Rest Pain Small Vessel Disease Ulcers	The BioArterial Plus Arterial Blood Flow Enhancement System is intended as adjunct therapy for patients with ischemic disease of the lower extremities, due to one or more of the following causes: Minor Amputations Angioplasty / Stent Failure Arteriopathic Wounds Graft Failure Intermittent Claudication Ischemia Night Pain Rest Pain Small Vessel Disease Ulcers.
Inflation Pressure	Calf: 120 mmHg Foot: 120 mmHg	Calf: 120 mmHg Foot: 120 mmHg
Cycle Time (approximate)	Sequential compression of the limbs (foot followed by calf) Compression: 3 seconds (± 0.5 sec) Non-Compression: 17 seconds (± 0.5 sec) Delay between Foot & Calf: 1 second (± 0.5 sec) Cycle: 20 seconds / 3 Cycles per minute	Sequential compression of the limbs (foot followed by calf) Compression: 3 seconds (± 0.5 sec) Non-Compression: 17 seconds (± 0.5 sec) Delay between Foot & Calf: 1 second (± 0.5 sec) Cycle: 20 seconds / 3 Cycles per minute
Electrical Safety	IEC 60601-1 (safety) UL60601-1 (safety) Class II,Type B CAN/CSA 22.2 IEC 60601-1-2 (Emissions) IEC 60601-1-2 (Immunity)	UL Std: 60601-1, Class II, Type B EN60601-1-2:2001
Power Rating	VascuComp – 01 Voltage: 100-120 VAC Freq: 60Hz Ph: 1 Current: 3.0A	BioArterial Plus Voltage: 120 VAC Freq: 60Hz Current: 0.5A

	VascuComp – 02 Voltage: 220-240 VAC Freq: 50/60Hz Ph: 1 Current: 1.5A	

VascuComp™ DVT Mode:

Parameter	VascuComp™ Compression Device	ThermoTek Inc., VascuTherm (K061866)
Intended use	Intermittent Pneumatic Compression	Intermittent Pneumatic Compression
Indications for Use	Decrease the risk of deep venous thrombosis (DVT). Aids the blood flow back to the heart. Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.	Decreases the risk of deep venous thrombosis, DVT Aids the blood flow back to the heart. Treat and assist healing of cutaneous ulceration (wounds), reduce wound healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.
Inflation Pressure	45mmHg (calf) 100mmHg (foot)	45 mmHg (calf) 100 mmHg (foot)
Cycle Time (approximate)	Inflation: 30 seconds Deflation: 30 seconds	Inflation: 30 seconds Deflation: 30 seconds
Electrical Safety	IEC 60601-1 (safety) UL60601-1 (safety) Class II,Type B CAN/CSA 22.2 IEC 60601-1-2 (Emissions) IEC 60601-1-2 (Immunity)	UL Std: 60601 Class II, Type B IEC 60601-1-2 (Emissions) IEC 60601-1-2 (Immunity)
Power Rating	VascuComp – 01 Voltage: 100-120 VAC **Freq: 60Hz Ph: 1** Current: 3.0A VascuComp – 02 Voltage: 220-240 VAC Freq: 50/60Hz Ph: 1 Current: 1.5A	VascuTherm Voltage: 100-120 VAC Freq: 60Hz Ph: 1 Current: 4.5A

VascuComp™ L Mode:

Parameter	VascuComp™ Compression Device	PBS (Petit Basci System) Model 701A (K060220)
Intended use	Intermittent, Sequential, Pneumatic Compression	Intermittent, Sequential, Pneumatic Compression
Indications for Use	Treatment of Venous disorders and dysfunction of the "muscle pump"	Treatment of Venous disorders and dysfunction of the "muscle pump"
Inflation Pressure	20 to 80 mmHg	20 to 80 mmHg
Electrical Safety	IEC 60601-1 (safety) UL60601-1 (safety) Class II,Type B CAN/CSA 22.2 IEC 60601-1-2 (Emissions) IEC 60601-1-2 (Immunity)	UL Std: 60601-1, Class II, CAN/CSA C22.2
Power Rating	VascuComp – 01 Voltage: 100-120 VAC Freq: 60Hz Ph: 1 Current: 3.0A VascuComp – 02 Voltage: 220-240 VAC Freq: 50/60Hz Ph: 1 Current: 1.5A	PBS Model 701A Voltage: 115 VAC Freq: 50/60 Hz Current: 2.0A

CONTRAINDICATIONS FOR USE

The patient should not use the Vascu Comp™ compression therapy system if the patient is suspected of or observed to have any of the following:

VascuComp™ AI Mode:

- Undesirable venous and lymphatic return (as with congestive heart failure)
- Deep vein thrombosis (suspected or present)
- Inflammatory Phlebitis
- Episodes of pulmonary embolism
- Sepsis in the limb
- Cellulitis without appropriate antibiotic coverage
- Immediately following skin grafts in/around treatment sides
- Pulmonary edema associated with congestive heart failure
- Acute thrombophlebitis

VascuComp™ DVT Mode:

- Presumptive evidence of congestive heart failure
- Suspected / observed pre-existing deep vein thrombosis or pulmonary emblosim
- Suspected/observed deep acute venal thrombosis (phlebothrombosis)
- Suspected/observed inflammatory phlebitis process
- Suspected/observed pulmonary edema
- Suspected/observed acute inflammations of the veins (thrombophlebitis)
- Suspected/observed decompensated cardiac insufficiency
- Suspected/observed arterial dysregulation
- Suspected/observed erysipelas
- Suspected/observed carcinoma and carcinoma metastasis in the affected extremity
- Suspected/observed decompensated hypertonia
- Suspected/observed acute inflammatory skin diseases or infection
- Suspected/observed venous or arterial occlusive disease
- Determine venous and lymphatic return is undesirable
- Poor Peripheral Circulation
- Severe Arteriosclerosis, or active infection

VascuComp™ L Mode:

- Known or suspected deep venous thrombosis
- Inflammatory Phlebitis
- Episodes of pulmonary embolism
- Pulmonary edema or congestive heart failure
- Severe arteriosclerosis or other ischemic vascular disease.
- Any circumstance where increased venous and lymphatic return is undesirable.

PERFORMANCE DATA

Non clinical performance testing was performed as part of a sequence of verification testing to validate the subject device, the VascuComp, meets the required specifications when compared to the predicates the PBS (Petit Basic System) Model 701A (K060220), ThermoTek VascuTherm (K061866) and Bio Compression Systems, Inc., BioArterial Plus (K072666) predicate devices.

The objective of the first tests were to verify that the therapy pressure level and cycle times in regards to pneumatic compression therapy functionality for the treatment of edema and lymphedema on the VascuComp and four-chamber full leg garment is satisfactory as compared to the published and observed therapy modality of the PBS (Petit Basci System) Model 701A pedicate device.

Conclusions
Over a minimum of 2 compression cycles, VascuComp with a the four-chamber full leg garment showed that the cycle pressure and time passed all preset criteria from the PBS (Petit Basci System) Model 701A predicate device literature.

The objectives of the second tests were to verify that the therapy pressure level and cycle times in regards to pneumatic compression therapy functionality to reduce the risk of DVT formation on the VascuComp and ThermoTek predicate foot wrap and calf wrap is satisfactory as compared to the published and observed therapy modality of the ThermoTek, VascuTherm predicate device.

Conclusions
Use of the ThermoTek predicate foot wrap and calf wrap accessory on the VascuComp device yielded compression data that meets the preset criteria for proper DVT therapy modality from the ThermoTek predicate device. The VascuComp DVT wraps are identical in treatment area and therapy modality to the predicate device, the VascuTherm. The data from this test showed that the VascuComp device passed all preset test criteria as compared to ThermoTek, VascuTherm (K061866) predicate device literature.

The objectives of the third tests were to verify that the therapy pressure level and cycle times in regards to pneumatic compression therapy functionality for the enhancement of arterial blood flow on the VascuComp and a sequential compression foot – calf garment is satisfactory as compared to the published and observed therapy modality of the Bio Compression Systems, Inc., BioArterial Plus (K072666) predicate device.

Conclusions
Over a minimum of three compression cycles, VascuComp with a foot-calf garment showed that the treatment pressure and time passed all preset criteria form the Bio Compression Systems, Inc., BioArterial Plus (K072666) predicate device literature.

The objectives of the fourth test were to verify conformance of the VascuComp I and II devices to IEC 60601-1 safety and IEC60601-1-2 radiated and conducted emissions standard.

Conclusions
The device met the construction, dialetric testing and electrical leakage as specified in the IEC 60601-1 standard. Pre scan data of conducted and radiated emissions of the device also confirmed that it met the IEC60601-1-2 EMC/EMI standards.

STATEMENT OF SUBSTANTIAL EQUIVALENCE:

Based upon the safety and performance testing, compliance with voluntary standards, and comparison to the predicate devices in terms of features, functionality and non clinical comparison testing, the manufacture believes that the VascuComp™ therapy system is substantially equivalent to the predicate devices, and does not raise any new risks of safety of effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Thermo Tek, Inc.
c/o Mr. Bhavesh V. Sheth
Regulatory Reviewer
Intertek Testing Services, Inc.
2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087

DEC 10 2010

Re: K103247
VascuComp (Models 01 and 02)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: November 2, 2010
Received: November 3, 2010

Dear Mr. Sheth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4. Indications for Use Statement

DEC 1 0 2010

510(k) Number (if known): K103247

Device Name: VascuComp™-01 and VascuComp™-02

Indications for Use:

VascuComp™ AI Mode:

The VascuComp™ compression system in AI Mode is used as an adjunct therapy for patients with ischemic disease of the lower extremities, due to one or more of the following causes:

- Minor Amputations
- Angioplasty / Stent Failure
- Arteriopathic Wounds
- Graft Failure
- Intermittent Claudication
- Ischemia
- Night Pain
- Rest Pain
- Small Vessel Disease
- Ulcers

VascuComp™ DVT Mode:

- Decrease the risk of deep venous thrombosis (DVT).
- Aids the blood flow back to the heart.
- Treat and assist healing of cutaneous ulceration (wounds), reduce wound healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.

VascuComp™ L Mode:

- Treatment of Venous disorders and dysfunction of the "muscle pump".

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vellucci

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103247